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GP 1654

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Kuhner et al.

Attorney Docket No.:

HER-0052

Application No.:

09/881,954

Examiner:

Audet, M.

Filed:

1

June 15, 2001

Group:

1654

Title:

PEPTIDES, COMPOSITIONS, AND METHODS

FOR THE TREATMENT OF BURKHOLDERIA

**CEPACIA** 

**CERTIFICATE OF MAILING** 

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail to: Commissioner for Patents, P.O Box 1450, Alexandria, VA 22313-1450 on December 3, 2003.

Signed: Thacker

Miriam Thacker

## RESPONSE TO RESTRICTION REQUIREMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Dear Sir:

In response to the Election/Restriction Requirement mailed October 3, 2003, Applicant provisionally elects with traverse Group I (claims 1-21, and 28-34), with Group II claims 22-27 withdrawn from consideration. Applicant concurs in the withdrawal of the above Group II claims, subject to the reservation of the right to file a divisional application during the pendency of the present application.

The Examiner correctly notes that a restriction requirement may be proper when it can be shown that the separately grouped inventions are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. The examples presented in MPEP 806.04 are (1) "an article of apparel such as a shoe, and locomotive bearing" and (2) a process of painting a house and a process of boring a well." MPEP 808.01 points out

that "independent inventions" are not "connected in design, operation or effect under the disclosure of the particular application." According to the MPEP, this is a rare situation.

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It is respectfully submitted that the claim groups as identified by the Examiner are not unrelated. Each has a common core set of modified peptides possessing antimicrobial activity, with the concomitant use of these peptides to combat microbes.

Further, in order for a restriction requirement to be proper, there must be a serious burden on the Examiner. According to MPEP 803, "if the search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to independent or distinct inventions."

In this case, any appropriate search of the Group I claims should reasonably cover the inventions recited in the Group II claims as well. As indicated, both inventions involve a *common core* set of modified peptides pertaining to use as antimicrobials. Hence, it is respectfully submitted that it would not be a serious burden on the Examiner to search both claim Groups I and II.

In the present case, the Examiner has also argued restriction under the "separate status in the art" feature. According to the separate status in the art feature of MPEP 808.02, restriction may be proper when:

"each subject can be shown to have formed a separate subject for inventive effort when an explanation indicates a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search."

The Examiner has done nothing to substantiate that the pending claims have "separate status in the art," and has not shown the need for a separate field of search. By way of argument, and evidence to the contrary, the specific hexapeptides as referred to by the Examiner are Markush-type claims, and as properly supported by the disclosure, are an acceptable way to claim an invention and present claims of differing scope. As stated in MPEP 803.02, "if the members of the Markush group are...so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they are directed to independent and distinct inventions. In such a case, the examiner....will not require restriction."

In addition, the Applicant contends that the invention contains a distinguishable core structure that runs through the respective compositions claimed. The peptides of the present invention may be modified at the N- and/or C-terminus, and any position on at least one amino acid residue. These modified peptides may be represented by Formulae I and II, which display a common core R1 (C=O)- group bound to the alpha nitrogen of the N-terminal amino acid of the peptide. The NH2 group (Formula I) or the –NH-R2 group (Formula II) are bound to the same carbon of the alpha carboxyl group of the C-terminal amino acid. Accordingly, it is submitted that the restriction requirement is improper due to the Examiner's failure to effectively illustrate that the claims have attained separate status in the art.

Withdrawal of the restriction/election requirement is respectfully submitted. Should it be determined that a telephone interview would expedite review, the undersigned may be contacted at (602)262-5905.

If any fees are due in connection with the filing of this Response to Restriction Requirement, the Commissioner is hereby authorized to charge such fees to Deposit Account 501234.

Respectfully submitted,

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3